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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,578	10/26/2001	Jeffrey S. Kiel	KIEL / 02	4696
26875	7590	12/23/2003	EXAMINER	
WOOD, HERRON & EVANS, LLP 2700 CAREW TOWER 441 VINE STREET CINCINNATI, OH 45202			KWON, BRIAN YONG S	
			ART UNIT	PAPER NUMBER
			1614	
DATE MAILED: 12/23/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/047,578	KIEL ET AL.	
	Examiner Brian S Kwon	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 03 October 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-21,31-48 and 53 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-21,31-48 and 53 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 - a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) Interview Summary (PTO-413) Paper No(s) _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Summary of Action

- I. The rejection of claims 1-21, 31-48 and 53 under 35 USC 112, second paragraph, will not be maintained in light of Applicants' Remark.
- II. The rejection of claims 1-21, 31-48 and 53 under 35 USC 103(a) as being unpatentable over Gordziel (US 6287597) in view of Chopdekar et al. (US 5599846) is maintained for the reason of the record.

Status of Application

1. Acknowledgment is made of applicants' canceling of claims 22-30 and 49-52 in Applicants' Response to Office Action filed on October 03, 2003.
2. Applicants state in the response that the claim 31 is listed both as having been withdrawn and as having been rejected in the Office Action mailed on June 03, 2003. The Examiner inadvertently included the claim 31 as the non-elected claims (page 2, line 11 of O.A.).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-21, 31-48 and 53 is rejected under 35 USC 103(a) as being unpatentable over Gordziel (US 6287597) in view of Chopdekar et al. (US 5599846).

This rejection is analogous to the original rejection.

Response to Arguments

Applicants' arguments filed October 03, 2003 have been fully considered but they are not persuasive.

Applicant's argument takes position that the combination of Gordziel and Chopdekar references do not teach all the limitations of independent claims 1, 31, and 53 which require (i) a separate step of preparing a dispersion, including a dispersing agent, which is then added to a solution including the decongestant and antihistamine and (ii) the presence of dispersing agent that prevents the clumping and aggregation of the tannate salt formed when the first solution is transferred to the first dispersion in its claimed method step.

The examiner disagrees. Regardless of the characteristic of the claimed dispersing agent, magnesium aluminum silicate has been utilized in formulating a composition containing phenylephrine tannate and pyrilamine tannate in the prior art (Gordziel).

Therefore, the use of dispersing agent in making the claimed phenylephrine tannate and pyrilamine tannate containing composition would have been apparent to the person of ordinary skill in the relevant art. With the respect to the instantly claimed sequence of adding ingredients by creating separate step of mixing a dispersing agent and tannic acid in a suitable solvent, for example water, to generate the dispersion before adding it to the solution containing phenylephrine tannate and pyrilamine tannate, the examiner maintains that such selection of any order of mixing ingredients is *prima facie* obvious in the absence of new or unexpected results showing such step is critical.

Applicants allege that the prior art references in combination only teach a composition made by the old water route. As discussed in preceding comments, the instant specification fails to provide evidence indicating the criticality of the claimed step over the prior art. Therefore, one having ordinary skill in the art would have been expected at the time of the invention was made that the claimed invention of adding ingredients by creating separate step of mixing a dispersing agent, tannic acid and water before mixing it with phenylephrine tannate and pyrilamine tannate solution would have been determined in the prior art.

Applicants allege that examiner's contention that optimization of the specific amount of ingredients or pH of the composition would be obvious is unsupported in that these amounts are not taught by, nor suggested by, either reference. This argument is not persuasive. Those of ordinary skill in the art will readily optimize effective dosage amounts of well-known active and inactive ingredients in the composition comprising pyrilamine tannate and phenylephrine tannate without undue experimentation, especially in light of column 2, line 15 thru column 3, line 27 in Gordziel and column 2, lines 54-64.

As stated in the previous Office Action, the prior art does not disclose the claimed pH range. However, one having ordinary skill in the art would expect at the time of the invention was made that the instantly claimed pH would have been characteristics of the prior art. Generally, differences in pH will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such pH is critical.

Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable pH by routine experimentation.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703) 308-5377. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Brian Kwon

**ZOHREH FAY
PRIMARY EXAMINER
GROUP 1600**

